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DEPARTMENT OF HEALTH & HUMAN SERVICES
Food and Drug Administration
New England District

Food and Drug Administration
One Montvale Avenue
Stoneham, Massachusetts 02180
(781)279-1675 FAX: (781)279-1742

WARNING LETTER

December 9, 1998

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

NWE-03-99W

Timothy McKibben, CEO
Welcon, Inc.
505 Main Street
Fort Worth, Texas 76102

Dear Mr. McKibben:

During an inspection of your establishment located in Providence, Rhode Island, on October 28, 29, 30, and November 3, 1998, our Investigator determined that your establishment manufactures sterile irrigating syringes, urinary drainage bags, and Foley catheter trays. Sterile irrigating syringes, urinary drainage bags, and Foley catheter trays are devices as defined by Section 201 (h) of the Federal Food, Drug and Cosmetic Act, (the Act).

The above-stated inspection revealed that these devices are adulterated within the meaning of Section 501(h) of the Act, in that the methods used in, or the facilities or controls used for manufacturing, packing, storage, or installation are not in conformance with the Quality System Regulations (QSR) for Medical Devices Regulation, as specified in Title 21, Code of Federal Regulations (CFR), Part 820, as follows:

1. Failure of your Complaint Handling to ensure all complaints are processed in a uniform and timely manner, for example:
   a. "Complaint Report" #174, describes a leak in the Hue-Vu™ Urinary Drainage Bag (Code 2800). The "Quality Assurance Complaint Investigation Report" states, "Not a Quality Issue. Product returned to stock." No follow up investigation is provided in this report to show how your firm came to this conclusion. Further, the Return Goods Authorization (RGA) for Complaint

Report #174, identifies two (2) altogether different product codes (4136, and 6122) and the investigative reports list "various" as the code.

b. Failure to revise the Complaint Processing SOP dated January 6, 1992, to reflect the current practice in that complaints are now received at the Welcon facility in Texas and are then forwarded to the Welcon facility in Rhode Island for evaluation of quality issues.

c. Twenty-two (22) complaints were reviewed from March 1998 to the present and revealed that you failed to document the dates the Rhode Island facility received the complaints from the Texas facility. Further, the follow up investigations lacked the dates the customers were contacted, who was contacted, the explanations for some of the final conclusions, or who conducted the investigation at your firm.

d. Investigation of complaint RGA #132 confirms flash on product WO32. However, the lot number involved is not documented.

2. Failure to ensure that each Device Master Record (DMR) is prepared and approved, for example:

a. The Change Control Procedure dated November 14, 1994 was not followed for revising the manufacturing procedure. There have been nine (9) revisions in your DMR for the Foley Catheter Tray since March 1996. The two (2) most recent revisions have not been signed as approved and do not include revision numbers or dates.

b. The most recent DMR revision does not include the manufacturing procedure, and a separate procedure has not been written.

c. A shipping label is not referenced in the DMR, although two shipping labels are included in the file. The obsolete shipping label was not marked obsolete.

3. Control of electron beam sterilization of medical devices by the contract sterilizer ([redacted]) is inadequate.

a. The specifications for sterilization include minimum and maximum internal and surface doses, however the certificates of irradiation for [redacted] lists only the average surface doses. The average surface dose listed on the certificate of irradiation for product #6104 (Irrigation Tray with Piston Syringe) Lot 098BLO, is [redacted] which is the minimum surface dose permitted for this product.

b. There is no record of the sterilization validation results or protocol available at Welcon. The October 13, 1998 quarterly bioburden results averaged 1329.1 cfu/syringe, but this could not be compared to the bioburdens used for the validation.

c. There is no documentation of Welcon's review of the quarterly bioburden tests done by [redacted]

d. The quarterly bioburden results dated October 13, 1998 for product #6104 list lot number 0698EYO. Lot number 0698EYO actually corresponds to product #37-670, Irrigating Syringes. There is no indication that the discrepancy was noted by Welcon.

4. Failure to control labeling and packaging operations to prevent labeling mixups, for example:
   a. Four (4) in house carrier boxes on a pallet in the Syringe Assembly Room containing Thumb Control Syringes #33 from Lot 1198AXO manufactured on October 25, 1998, were labeled with various product labels, for example product #505, Lots 0998CCO and 1098ACO; and product #799, Lot 0898FAO.
   b. Boxes containing black grommets #573, lot 1198ALO used in irrigation syringes being produced on molding machine #2 on October 28, 1998, were labeled with various lot numbers, some correct and some incorrect (i.e., lots 1198ALO, 1098ARO etc.).
   c. Boxes containing long tip barrels, product #799, Lot 1198ATO, being produced on molding machine #12 on October 28, 1998, were labeled with various products and lot numbers. The barrels are used in the irrigation syringes.
   d. Boxes are reused prior to removing or covering the label for the products previously stored in the boxes.

5. Failure to control nonconforming product in that product that does not conform to specified requirements is stored next to accepted product, for example:
   a. Eight (8) boxes of various products stored outside the Laboratory door were identified as scrap. Of the eight (8) boxes three (3) were labeled as "Rejected." The other five (5) boxes were labeled as various accepted products.
   b. Scrap materials were stored in boxes labeled as various accepted products, next to accepted raw materials and components in the first floor loading dock area on October 28, 1998. For example, boxes on one pallet identified as containing scrap, had acceptable component labels for Thumb Control Piston Syringes #WO32, Lot 0898DLO. Further, one row contained both scrap products and accepted components.
   c. A box containing acceptable long tip barrels (#799B) was stored on top of a pallet containing regrind in the upper warehouse on the first floor on October 28, 1998. The label on the box of barrels was for product #0505, Lot 0998CCO, but was crossed out with "799B" written over it.

6. Failure to ensure that mixups, damage, deterioration, contamination, or other adverse effects to product do not occur during the storage of product. For example:

a. There is no divider on the first floor between the Welcon storage area and the area leased to [redacted] Welcon products are stored immediately next to the [redacted] products.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the FDA 483 issued at the conclusion of the inspection may be symptomatic of serious underlying problems in your establishment's manufacturing and quality assurance systems. You are responsible for investigation and determining the causes of the violations identified by the FDA. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts. Additionally, no premarket submissions for Class III devices to which the QSR deficiencies are reasonably related will be cleared until the violations related to the subject devices have been corrected. Also, no requests for Certificates to Foreign Governments will be approved until the violations related to the subject devices have been corrected.

We acknowledge that George A. Hird promised corrections and a written response to the FDA-483 that was issued to him at the conclusion of the inspection.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to seizure, injunction, and /or civil penalties.

Please notify this office in writing within fifteen (15) working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to identify and make corrections to any underlying systems problems necessary to assure that similar violations will not recur. If corrective action cannot be completed within fifteen (15) working days, state the reason for the delay and the time within which the corrections will be completed.

Your response should be sent to Bruce R. Ota, Compliance Officer, Food and Drug Administration, One Montvale Avenue, Stoneham, Massachusetts 02180.

Sincerely,

John R. Marzilli
District Director
New England District Office